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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,056	09/20/2001	Mark L. Tykocinski	285332-00002-2	6690

3705 7590 01/28/2003

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/28/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/957,056

Applicant(s)

TYKOCINSKI ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-44, 46, 47 and 49-61 is/are pending in the application.
- 4a) Of the above claim(s) 24-36 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 and 51-61 is/are allowed.
- 6) ☒ Claim(s) 37-44, 46, 47, 49 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Claims 23-44, 46, 47 and 49-61 are pending.
Claims 45 and 48 have been cancelled.
Claims 51-61 have been added.
Claims 23 and 37 have been amended.
Claims 24-36, drawn to non-elected inventions are withdrawn from examination.
Claims 23, 37-44, 46, 47 and 49-61 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. Applicants' have amended the first line of specification, which reflects the current status of the parent nonprovisional application.
4. Applicants' have amended the title of the invention so that it is clearly descriptive and indicative of the invention to which the claims are directed.
5. The use of the trademark FACStar® on page 10, line 21 has been noted in this application and has been capitalized and accompanied by the generic terminology.

Withdrawn Objections

Specification

6. The disclosure is no longer objected to because the informalities listed in Paper number 6, mailed June 18, 2002, page 3, paragraph 7 have been corrected.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

7. The rejection of claims 23 and 37-44, 46, 47, 49 and 50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' arguments. Claims 45 and 48 have been cancelled.

Maintained Rejections

Claim Rejections - 35 USC § 112

8. The rejection of claims 37-44, 46, 47, 49 and 50 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cancer vaccine comprising a cell with a first protein (lipidated protein) and second proteins (several fusion proteins) to vaccinate subjects with L5178Y-R and T-50 tumor cells (see Examples 3-5, pages 17-19), does not reasonably provide enablement for the use of a cancer vaccine comprising several cell types in all types of cancer is maintained. The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to practice the invention commensurate in scope with these claims. Claims 45 and 48 have been cancelled.

Applicants argue that "...one skilled in the art would be able to determine which type of tumor or other antigen presenting cell..." and "[o]ne skilled in the art could easily screen various tumor or other antigen presenting cells or combinations of cells having transferred fusion proteins for their ability to evoke an immune response and reduce or eliminate tumors *in vivo*; such testing is routine and not undue under the standard set forth in *In re Wands*." These arguments have been considered but found to be unpersuasive.

Applicants' disclosure lacks sufficient guidance regarding which fusion proteins of the claimed cancer vaccine would be effective in invoking an immune response, such that it is useful for vaccination of cancers. The broadness of the claims, in particularity, claim 37 encompasses an infinite number of fusion proteins, which according to Applicants could be within the cancer vaccine. However, there is no accompanying data or guidance suggestive of the effectiveness of the huge number of possible proteins, which are germane to the claimed invention. And while screening assays are routine in the art, it is not reasonable to screen a plethora of possible combinations, which are useful for vaccination particularly in view that the state of the art for cancer vaccination is unpredictable. Applicants have not provided any evidence or guidance that is predicative of the expectation of success. In view of the above and the reasons listed in Paper # 6, one of skill in the art would be forced into undue experimentation to practice implementation of the claimed invention.

Allowable Subject Matter

9. Claims 23 and 51-61 are allowed.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
January 24, 2003


ANTHONY C. CAPUTA
INVENTORY PATENT EXAMINER
TECHNOLOGY CENTER 1600